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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,694	02/10/2004	Irit Gil-Ad	25464X	8587

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Gary M. Nath
NATH & ASSOCIATES PLLC
6th Floor
1030 15th Street, N.W.
Washington, DC 20005

EXAMINER	
OLSON, ERIC	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,694	GIL-AD ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10432875.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

This application is a Continuation-in-part of application 10/432875, filed September 16,2003, currently pending, which is a national stage entry of PCT/IL01/01105, filed November 29, 2001. This application also claims benefit of foreign application IL139975, filed November 29, 2000. Claims 1-60 are pending in this application and subject to restriction herein.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a pharmaceutical composition comprising a topically acceptable carrier and a cyclic psychotropic agent other than doxepine or tomoxetine, classified in class 514, subclass 215, 217, 239.2, 320, 384, 438, 450, 506, 647, and 648, for example.

II. Claims 17-31 and 50-58, drawn to a method for treating a hyperproliferative disease by topically administering a cyclic psychotropic agent, classified in class 514, subclass 215, 217, 239.2, 320, 384, 438, 450, 506, 647, and 648, for example.

III. Claims 32-49, drawn to a method for treating inflammation by topically administering a cyclic psychotropic agent, classified in class 514, subclass 215, 217, 239.2, 320, 384, 438, 450, 506, 647, and 648, for example.

IV. Claims 59-60, drawn to a method of identifying and screening for an active agent for the treatment of a dermatological/mucosal disease, classified in

class 514, subclass 215, 217, 239.2, 320, 384, 438, 450, 506, 647, and 648, for example.

Claim 16 links inventions II-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the indication of allowability of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case a different product could be used for the claimed therapeutic methods. For example, cryotherapy with liquid nitrogen may be used to control nonmalignant proliferative dermatological disorders, while topical corticosteroids or other anti-inflammatory drugs may be used to control inflammation, and dacarbazine may be used to sensitize skin cancer to chemotoxic drugs.

The search field for a compound is non-coextensive with the search field for a method of treating a patient employing the same composition. A reference to the composition herein would not necessarily be a reference to the method of treatment herein under 35 USC 103 because a search indicating the process or method is novel or unobvious would not extend to a holding that the product is novel or unobvious whereas a search indicating that the product is known or would have been obvious would not extend to a holding that the process or method is known and would have been obvious. Note that the search is not limited to patent files. Thus an undue burden on the Office is seen for the search of all inventions herein, as discussed in the Requirement for Restriction above.

Because these inventions are distinct for the reasons given above and the search required for Groups II-IV is not required for Group I, restriction for examination purposes as indicated is proper.

Inventions II and III are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the disorders to be treated are different. A method of treating inflammation is patentably distinct from a method of treating proliferative disorders or malignant skin cancers. Inflammation is a natural physiological response while proliferative disorders and cancer are the result of abnormal cell division. Therefore pharmaceutical agents expected to treat inflammation (e.g. corticosteroids) are not expected to be useful against proliferative disorders and cancer. Similarly, surgery, radiation, and cytotoxic chemotherapy, which are all useful for the treatment of cancer and proliferative disorders are not useful for the treatment of inflammation. On a more basic level, the goal of therapy for proliferative disorders and cancer is to destroy a population of abnormal cells, while the goal of therapy for inflammation is to induce inflamed tissue to return to its normal, noninflammatory state. Therefore a method of treating inflammation does not overlap in scope with, and has a materially different design, mode of operation, function, and effect from a method of treating cancer or proliferative disorders.

Because these inventions are distinct for the reasons given above and the search required for group II is not required for group III, restriction for examination purposes as indicated is proper.

Inventions II-III and IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of groups II-III are directed to methods of treating diseases in a subject, while group IV is directed to a method of identifying and screening for an active agent for the treatment of dermatological diseases. A method of treating a disease is distinct from a method of identifying an active agent because the materials and subject population differ between the two groups. A method of treating a disease is practiced on a living subject suffering from the disease, using an active agent known to be active against the disease. A method of screening may be practiced on any one of the following: an animal model of experimentally induced disease, an *in vitro* cell culture, or an *in vitro* assay of receptor binding or enzyme inhibition. In particular, in the field of cancer therapy, the use of *in vitro* tumor cell cultures as experimental models for screening candidate compounds is a commonly accepted practice. For potential anti-inflammatory compounds, there exist biological targets such as COX enzymes and cytokines which may be used as *in vitro* screening targets. Furthermore, the screening protocol will

utilize compounds not yet known to possess any therapeutic utility, while the method of treating diseases will utilize only compounds known to possess a therapeutic utility. Thus any compound which is suitable for the therapeutic method is therefore no longer a drug candidate for the method of screening, and a compound of unknown utility which is a candidate for screening is not a suitable therapeutic for the treatment of disease.

Because these inventions are distinct for the reasons given above and the search required for groups II-III is not required for group IV, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because the above restriction requirement is complex, a telephone call to applicant's agent to request an oral election was not made. (See MPEP 812.01)

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday through Friday from 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eric Olson
Patent Examiner
AU 1623
8/29/06

Anna Jiang
Supervisory Patent Examiner
AU 1623